Commonwealth of Virginia

Department of General Services
Division of Consolidated Laboratory Services

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

Y N N/A

QUALITY SYSTEM

1247 ☐ ☐ ☐ 600 B — The quality system shall be appropriate to the type, range and volume of testing, analysis, measurement or monitoring performed by the laboratory.

1248 ☐ ☐ ☐ 600 C — The quality system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel. All personnal concerned with testing and calibration activities within the laboratory shall familiarize themselves with the quality documentation and implement the policies and procedures of their work.

1249 ☐ ☐ ☐ 600 D — If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not clear which standard or requirement is more stringent, the standard or requirement from the method or regulation is followed.

SOP

1298 ☐ ☐ ☐ 660 B 4 — Laboratory support activities: The laboratory shall retain the following documents and data: Archived standard operating procedures.

1341 ☐ ☐ ☐ 730 A 1 — The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of samples, and for calibration or testing, where the absence of such instructions could jeopardize the calibrations or tests.

1342 ☐ ☐ ☐ 730 A 2 — All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up to date and be readily available to the staff.

1343 ☐ ☐ ☐ 730 B 1 — Laboratories shall maintain SOPs that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods. These documents, for example, may be equipment manuals provided by the manufacturer or internally written documents. The test methods may be copies of published methods as long as changes or selected options in the methods are documented and included in the laboratory methods manual.

1344 ☐ ☐ ☐ 730 B 2 — The SOPs shall be organized. Each SOP shall clearly indicate the effective date of the document, the revision number and the signature or signatures of the responsible laboratory manager or managers.

1345 ☐ ☐ ☐ 730 B 3 — Copies of all SOPs shall be accessible to all personnel.

1346 ☐ ☐ ☐ 730 C 1 — SOPs for laboratory methods: The laboratory shall have and maintain an SOP for each certified analyte or test method.

1347 ☐ ☐ ☐ 730 C 2 — SOPs for laboratory methods: This SOP may be a copy of a published or referenced method or may be written by the laboratory. In cases where modifications to the published method have been made by the laboratory or where the referenced test method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described.

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

Y N N/A

SOP

1348 ☐ ☐ ☐ 730 C 2

SOPs for laboratory methods: Each test method shall include or reference where applicable:
___Identification of the test method;
___Applicable matrix or matrices;
___Limits of detection or quantitation;
___Scope and application, including parameters to be analyzed;
___Summary of the test method;
___Definitions;
___Interferences;
___Safety;
___Equipment and supplies;
___Reagents and standards;
___Sample collection, preservation, shipment and storage;
___Quality control;
___Calibration and standardization;
___Procedure;
___Data analysis and calculations;
___Method performance;
___Pollution prevention;
___Data assessment and acceptance criteria for quality control measures;
___Corrective actions for out-of-control data;
___Contingencies for handling out-of-control or unacceptable data;
___Waste management;
___References; and,
___Any tables, diagrams, flowcharts and validation data.

1349 ☐ ☐ ☐ 730 D 1

Test methods. Laboratories shall use (i) promulgated test methods in accordance with the Code of Federal Regulations; (ii) test methods stated in any current permit issued by Virginia Air Pollution Control Board, the Virginia Waste Management Board, or the State Water Control Board; or (iii) alternate test procedures approved by the board using the permit or the Department of Environmental Quality, including applicable quality assurance requirements, and sample preservation, container, storage, and holding time requirements.

1350 ☐ ☐ ☐ 730 D 2

Test methods. The laboratory shall use appropriate test methods and procedures for all tests and related activities within its responsibility (including sample handling, transport and storage, preparation and analysis). The method and procedures shall be consistent with the accuracy required and with any standard specifications relevant to the calibrations or tests concerned.

1351 ☐ ☐ ☐ 730 D 3

Test methods. When the use of reference test methods for a sample analysis is mandated, only those methods shall be used.

1352 ☐ ☐ ☐ 730 D 4

Test methods. Where test methods are employed that are not required, as in the Performance Based Measurement System approach, the methods shall be fully documented and validated (see 730 E).

FACILITIES

1327 ☐ ☐ ☐ 710

Laboratory accommodations, test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of tests. Work areas include: access and entryways to the laboratory; sample receipt areas; sample storage areas; chemical and waste storage areas; and data handling and storage areas.

1328 ☐ ☐ ☐ 710 1

Environment and work areas. The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

1329 ☐ ☐ ☐ 710 2

Environment and work areas. The laboratory shall provide for the effective monitoring, control and recording of environmental conditions as appropriate. Such environmental conditions may include biological sterility, dust, electromagnetic interference, humidity, mains voltage, temperature, and sound and vibration levels.

1330 ☐ ☐ ☐ 710 3

Environment and work areas. In instances where monitoring or control of any environmental conditions are specified in a test method or by regulation, the laboratory shall meet and document adherence to the laboratory facility requirements.

1331 ☐ ☐ ☐ 710 4

Environment and work areas. There shall be effective separation between neighboring areas in which there are incompatible activities including culture handling or incubation areas and volatile organic chemical handling areas. The laboratory shall take measures to prevent cross-contamination.

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

	Y	N	N/A		
FACILITIES					
1332	☐	☐	☐	710 5	Environment and work areas. Access to and use of all areas affecting the quality of these activities shall be defined and controlled.
1333	☐	☐	☐	710 6	Environment and work areas. Adequate measures shall be taken to ensure good housekeeping in the laboratory and to ensure that any contamination does not adversely affect data quality.
1334	☐	☐	☐	710 7	Environment and work areas. Work spaces shall be available to ensure an unencumbered work area. Work areas include: access and entryways to the laboratory; sample receipt areas; sample storage areas; chemical and waste storage areas; and data handling and storage areas.
1428	☐	☐	☐	750 C 8	Quality assurance. All laboratories shall have detailed written protocols in place to monitor the following quality controls: Measures to assure constant and consistent test conditions (both instrumental and environmental) where required by the test method such as temperature, humidity, light, or specific instrument conditions.
LABORATORY MANAGER					
1225	☐	☐	☐	200 A 1	Each environmental laboratory shall designate a person to be responsible for the general oversight of the operation of the laboratory in accordance with this chapter, including the day-to-day functioning and administration of the laboratory, the technical operations, supervision of laboratory procedures, reporting of laboratory results, and implementation of any corrective actions.
1226	☐	☐	☐	200 B 1	For an environmental laboratory that performs procedures beyond simple test procedures, a laboratory manager shall have two years of experience managing an environmental laboratory or performing the analyses for which the environmental laboratory seeks certification or both.
1227	☐	☐	☐	200 B 2	For an environmental laboratory that performs only simple test procedures, there are no qualification requirements for a laboratory manager except that the responsible official shall designate the laboratory manager.
1228	☐	☐	☐	200 B 3	A full-time employee of a drinking water or wastewater treatment facility who holds a valid treatment plant operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational and experience requirements serving as the laboratory manager of the certified laboratory devoted exclusively to the examination of environmental samples taken within such facility system and limited to the scope of that facility's regulatory permit.
1229	☐	☐	☐	200 B 4	A full-time employee of an industrial waste treatment facility with a minimum of one year of experience under supervision in environmental analysis shall be deemed to meet the requirements for serving as the laboratory manager of a certified laboratory devoted exclusively to the examination of environmental samples taken within such facility for the scope of that facility's regulatory permit.
1239	☐	☐	☐	230	When the laboratory manager will be absent for a period exceeding 15 consecutive calendar days, the laboratory shall designate a qualified replacement to perform the manager's function.
QUALITY MANAGER					
1230	☐	☐	☐	210 A	The laboratory shall have a quality assurance officer who shall be responsible for the quality system and its implementation. Where staffing is limited, the quality assurance officer may also be the laboratory manager. The quality assurance officer may be employed on a part-time basis or be a consultant.
1231	☐	☐	☐	210 B	The quality assurance officer shall have documented training or experience in quality assurance and quality control procedures and be knowledgeable in the quality system as defined in 1VAC30-45-600 et seq.
1232	☐	☐	☐	210 B	The quality assurance officer shall have a general knowledge of the analytical test methods for which data review is performed.
1233	☐	☐	☐	210 C	The responsibilities of the quality assurance officer shall include, but not be limited to, the implementation and oversight of the quality system, the implementation of new quality assurance and control practices, periodic audits of the quality system in place, periodic review of final data reports, and documentation of laboratory quality system deficiencies.
1275	☐	☐	☐	610 D 1	The quality assurance officer shall review the laboratory's quality assurance program, manual and any related documentation whenever there is any change in test methods employed by the laboratory, change in equipment, or any other change in the laboratory that affects the quality assurance program.
MANAGEMENT REVIEW					
1311	☐	☐	☐	670 B 1	The laboratory management shall conduct a review, at least annually, of its quality system and its testing and calibration activities to ensure its continuing suitability and effectiveness, and to introduce necessary changes or improvements in the quality system and laboratory operations.

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

Y N N/A

MANAGEMENT REVIEW

1312 ☐ ☐ ☐ 670 B 2 — The managerial review shall take account of reports from managerial and supervisory personnel, the outcome of recent internal audits, assessments by external bodies, the results of inter-laboratory comparisons or proficiency tests, corrective actions and other relevant factors.

1313 ☐ ☐ ☐ 670 B 3 — The laboratory shall have a procedure for review by management and maintain records of review findings and actions.

METHOD VALIDATION

1222 ☐ ☐ ☐ 70 E — An owner of a certified noncommercial environmental laboratory shall follow the process set out in 1VAC30-45-90 B to add a new matrix, technology/method, an analyte or analyte group, modify a test method or institute use of a method or technology not in the laboratory's standard operating procedures, including alternative test methods or procedures.

1440 ☐ ☐ ☐ 760 B 3 A 1, 2 — Evaluation of precision and bias. Standard methods. The laboratory shall evaluate the precision and bias of a standard method for each analyte of concern for each quality system matrix according to either of the following:
(1) The single-concentration four-replicate recovery study procedures in 1VAC30-45-730 F; or
(2) An alternate procedure documented in the quality manual when the analyte cannot be spiked into the sample matrix and quality control samples are not commercially available.

1441 ☐ ☐ ☐ 760 B 3 B 1 — Evaluation of precision and bias. Nonstandard methods. For laboratory-developed test methods or nonstandard test methods that were not in use by the laboratory before July 2003, the laboratory shall have a documented procedure to evaluate precision and bias.

1442 ☐ ☐ ☐ 760 B 3 B 1 — Evaluation of precision and bias. Nonstandard methods. The laboratory shall also compare results of the precision and bias measurements with criteria given in the reference method or criteria established by the laboratory.

1443 ☐ ☐ ☐ 760 B 3 B 2 — Evaluation of precision and bias. Nonstandard methods. The precision and bias measurements shall evaluate the method across the analytical calibration range of the method.

1444 ☐ ☐ ☐ 760 B 3 B 2 — Evaluation of precision and bias. Nonstandard methods. The laboratory shall also evaluate precision and bias in the relevant quality system matrices and shall process the samples through the entire measurement system for each analyte of interest.

SAMPLES

1293 ☐ ☐ ☐ 660 A 1 — The laboratory shall maintain a record of all procedures to which a sample is subjected while in the possession of the laboratory. These shall include but are not limited to all records pertaining to sample preservation, identification, receipt, acceptance or rejection, log-in, storage and tracking. The laboratory shall maintain sampling information on each sample. This includes time and date of collection, type of sample (grab or composite), type of container, sampling point and preservation.

1294 ☐ ☐ ☐ 660 A 2 — The laboratory shall have documented procedures for the receipt and retention of samples, including provisions necessary to protect the integrity of the samples.

1603 ☐ ☐ ☐ 850 1 — Sample tracking. The laboratory shall have a documented system for uniquely identifying the items to be tested to ensure that there can be no confusion regarding the identity of such items at any time.

1604 ☐ ☐ ☐ 850 1 — Sample tracking. This system shall include identification for all samples, subsamples and subsequent extracts or digestates or both.

1605 ☐ ☐ ☐ 850 1 — Sample tracking. System laboratories shall use a permanent chronological record such as a logbook or electronic database to document receipt of all containers.

1606 ☐ ☐ ☐ 850 1 — Sample tracking. This sample receipt log shall record the following at a minimum:
__ name of facility where sample was taken,
__ date and time of laboratory receipt,
__ unique laboratory ID code, and
__ signature or initials of the person making the entries.

1615 ☐ ☐ ☐ 850 4 A — Storage conditions. The laboratory shall have documented procedures and appropriate facilities to avoid deterioration, contamination or damage to the sample during storage, handling, preparation, and testing. Any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded.

1616 ☐ ☐ ☐ 850 4 B — Storage conditions. The samples shall be stored according to the conditions specified by preservation protocols.

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

	Y	N	N/A		
SAMPLES					
1617	☐	☐	☐	850 4 B 1	Storage conditions. Samples that require thermal preservation shall be stored under refrigeration that is within 2Â° C of the specified preservation temperature unless method specific criteria exist. For samples with a specified storage temperature of 4Â° C, storage at a temperature above the freezing point of water to 6Â° C shall be acceptable.
1618	☐	☐	☐	850 4 B 2	Storage conditions. Samples shall be stored away from all standards, reagents, food and other potentially contaminating sources.
1619	☐	☐	☐	850 4 B 2	Storage conditions. Samples shall be stored in such a manner to prevent cross contamination.
1620	☐	☐	☐	850 4 C	Storage conditions. Sample fractions, extracts, leachates and other sample preparation products shall be stored according to 1VAC30-45 850 4 a, or according to specifications in the test method.
1621	☐	☐	☐	850 4 D	Storage conditions. Where a sample or portion of the sample is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.
1622	☐	☐	☐	850 4 D	Storage conditions. Where a sample or portion of the sample is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.
1623	☐	☐	☐	850 5	Sample disposal. The laboratory shall have standard operating procedures for the disposal of samples, digestates, leachates and extracts or other sample preparation products.
SAMPLE RECEIVING					
1607	☐	☐	☐	850 2	Sample Acceptance Policy. The laboratory shall have a written sample acceptance policy that clearly outlines the circumstances under which samples shall be accepted or rejected.
1608	☐	☐	☐	850 2	Sample Acceptance Policy. The policy shall ensure that only properly obtained samples with appropriate sampling records (see 1VAC30-45-640 B) are analyzed and that the samples are handled properly.
1609	☐	☐	☐	850 2	Sample Acceptance Policy: This sample acceptance policy shall be made available to sample collection personnel.
1610	☐	☐	☐	850 2	Sample Acceptance Policy. The policy shall include elements such as appropriate documentation of the sample's identification, use of appropriate sample containers, adherence to specified holding times, adequate sample volume to perform necessary tests, and procedures to be used when samples show signs of damage, contamination or inadequate preservation.
1611	☐	☐	☐	850 3 A	Sample handling protocols. Upon receipt, the condition of the sample, including any abnormalities or departures from standard condition as prescribed in the relevant test method, shall be recorded. All items specified by the sample acceptance policy shall be checked.
1612	☐	☐	☐	850 3 B	Sample handling protocols. All samples that require thermal preservation shall be considered acceptable if the arrival temperature is either within 2Â°C of the required temperature or the method specified range. For samples with a specified temperature of 4Â°C, samples with a temperature of ranging from just above freezing temperature of water to 6Â°C shall be acceptable. Samples that are hand delivered to the laboratory immediately after collection or on the same day that are collected may not meet these criteria. In these cases, the samples shall be considered acceptable if there is evidence that the chilling process has begun such as arrival on ice. Thermal preservation is not required in the field if the laboratory receives the sample and either begins the analysis or refrigerates the sample within 15 minutes of collection.
1613	☐	☐	☐	850 3 C	Sample handling protocols. The laboratory shall implement procedures for checking chemical preservation using readily available techniques, such as pH or free chlorine prior to or during sample preparation or analysis.
1614	☐	☐	☐	850 3 D	Sample handling protocols. The results of all checks required by the sample acceptance policy and relevant test method shall be recorded.
SUBSAMPLING					
1368	☐	☐	☐	730 H	Sample aliquots. Where sampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, the laboratory shall use documented procedures and appropriate techniques to obtain representative subsamples.
DEMONSTRATION OF CAPABILITY					
1305	☐	☐	☐	660 D 2	Administrative records: The laboratory shall maintain the following administrative records: Records of demonstration of capability for each analyst or work cell.

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

	Y	N	N/A		
DEMONSTRATION OF CAPABILITY					
1353	☐	☐	☐	730 E 1	Demonstration of capability. Prior to acceptance and institution of any test method, satisfactory initial demonstration of method capability is required. This demonstration does not test the performance of the method in real world samples, but in an applicable and available clean quality system matrix sample (a quality system matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method), for example, drinking water, solids, biological tissue and air. Laboratories shall follow the procedure in subsection F (1VAC30-45-730 F) of this section to demonstrate capability.
1354	☐	☐	☐	730 E 2	Demonstration of capability. Ongoing demonstration of method performance, such as laboratory control samples, is required.
1355	☐	☐	☐	730 E 3	Demonstration of capability. In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for certification and there have been no significant changes in instrument type, personnel or method, the continuing demonstration of method performance and the analyst's documentation of continued proficiency shall be acceptable. The laboratory shall have records on file to demonstrate that an initial demonstration of capability is not required.
1356	☐	☐	☐	730 E 4	Demonstration of capability. In cases where a laboratory analyzes samples using a method that has not been in use by an individual in the laboratory for at least one 12-month period, another successful demonstration of capability in accordance with subsection F of this subsection shall be required for that individual to resume testing by the method.
1357	☐	☐	☐	730 E 5	Demonstration of capability. In all cases, the laboratory shall document each demonstration of capability as required by 1VAC30-45-730 G.
1358	☐	☐	☐	730 E 6	Demonstration of capability. The laboratory shall complete a demonstration of capability each time there is a change in instrument type, personnel, or test method, including the addition of an analyte to a certified test method.
1359	☐	☐	☐	730 F	Procedure for Demonstration of Capability. The laboratory may document that other approaches to demonstration of capability are adequate. This documentation shall be included in the laboratory's quality manual.
1360	☐	☐	☐	730 F 1	Procedure for Demonstration of Capability. A quality control (QC) sample may be obtained from an outside source or may be prepared by the laboratory using alternate source stock standards that are prepared independently from those used in instrument calibration.
1361	☐	☐	☐	730 F 2	Procedure for Demonstration of Capability. The analyte or analytes shall be diluted in a volume of clean quality system matrix sufficient to prepare four aliquots at the concentration specified, or if unspecified, to a concentration of 1-4 times the limit of quantitation.
1362	☐	☐	☐	730 F 3	Procedure for Demonstration of Capability. At least four aliquots shall be prepared and analyzed according to the test method either concurrently or over a period of days.
1363	☐	☐	☐	730 F 4	Procedure for Demonstration of Capability. Using all of the results, calculate the mean recovery in the appropriate reporting units (such as g/L) and the standard deviations of the population sample (n-1) (in the same units) for each parameter of interest.
1364	☐	☐	☐	730 F 4	Procedure for Demonstration of Capability. When it is not possible to determine mean and standard deviations, such as for presence or absence of the analyte and logarithmic values, the laboratory shall assess performance against established and documented criteria.
1365	☐	☐	☐	730 F 5	Procedure for Demonstration of Capability. Compare the information from section 1VAC30-45-730 F 4 to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory-generated acceptance criteria (if there are not established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.
1366	☐	☐	☐	730 F 6	When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst shall proceed according to either subdivision 6a or 6b of this subsection. a. Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with1VAC30-45-730 F 3. b. Beginning with 1VAC30-45-730 F 3, repeat the test for all parameters that failed to meet criteria. Repeated failure, however, confirms a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all compounds of interest beginning with 730 F 3.

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

Y N N/A

DEMONSTRATION OF CAPABILITY

1367 ☐ ☐ ☐ 730 G — Documentation of demonstration of capability: The laboratory shall document each demonstration of capability so that the following information shall be readily available for each employee:

__ 1. Analyst or analysts involved in preparation and analysis.
__ 2. Matrix.
__ 3. Analytes, class of analytes, measured parameters, or organisms.
__ 4. Identification of methods performed.
__ 5. Identification of laboratory-specific SOP used for analysis, including revision number.
__ 6. Date or dates or analysis.
__ 7. All raw data necessary to reconstruct and validate the analyses.
__ 8. Data evaluation required by 1VAC30-45-730 F.

INITIAL CALIBRATION

1382 ☐ ☐ ☐ 740 A — Measurement traceability and calibration - general requirements. All equipment used for environmental tests, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the environmental test or sampling shall be calibrated before being put into service and on a continuing basis. The laboratory shall have an established program and procedure for the calibration of its equipment. This includes balances, thermistors, thermometers and control standards. Such a program shall include a system for selecting, using, calibrating, checking, controlling, and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform environmental test.

1384 ☐ ☐ ☐ 740 B 2 — Traceability of calibration. The overall program of calibration or verification or both and validation of equipment shall be designed and operated so as to ensure that measurements made by the laboratory are traceable to national standards of measurement.

1388 ☐ ☐ ☐ 740 C 2 — Reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

1398 ☐ ☐ ☐ 740 D 2 A — Instrument calibration. If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not clear which standard or requirement is more stringent, the standard or requirement from the method or regulation is followed.

1399 ☐ ☐ ☐ 740 D 2 B (1) — Initial Instrument Calibration. The laboratory shall include or reference the details of the initial instrument calibration procedures, including calculations, integrations, acceptance criteria and associated statistics in the standard operating procedure for the test method. When initial instrument calibration procedures are referenced in the test method, then the laboratory shall retain referenced material and make it available for review.

1400 ☐ ☐ ☐ 740 D 2 B (2) — Initial Instrument Calibration. The laboratory shall retain sufficient raw data records to permit reconstruction of the initial instrument calibration (e.g., calibration date, test method, instrument, analysis date, each analyte name, analyst's initials or signature, concentration and response, calibration curve or response factor, or unique equation or coefficient used to reduce instrument responses to concentration).

1401 ☐ ☐ ☐ 740 D 2 B (3) — Initial Instrument Calibration. Sample results shall be quantitated from the initial instrument calibration and may not be quantitated from any continuing instrument calibration verification unless otherwise required by regulation, method, or program.

1402 ☐ ☐ ☐ 740 D 2 B (4) — Initial Instrument Calibration. All initial instrument calibrations shall be verified with a standard obtained from a second manufacturer or lot. Traceability shall be to a national standard, when available. This element does not apply to laboratories performing only simple procedures.

1403 ☐ ☐ ☐ 740 D 2 B (5) — Initial Instrument Calibration. Criteria for the acceptance of an initial instrument calibration shall be established (e.g., correlation coefficient and relative percent difference). The criteria used shall be 0.995 or greater for the calibration coefficient unless a different criterion is included in the method being used.

1404 ☐ ☐ ☐ 740 D 2 B (6) — Initial Instrument Calibration. Results of samples not bracketed by initial calibration standards (within calibration range) shall be reported as having less certainty (e.g., defined qualifiers or flags or explained in the case narrative). The lowest calibration standard shall be above the detection limit.

1405 ☐ ☐ ☐ 740 D 2 B (7) — Initial Instrument Calibration. If the initial instrument calibration results are outside established acceptance criteria, corrective actions shall be performed. Data associated with an unacceptable initial instrument calibration shall not be reported.

1406 ☐ ☐ ☐ 740 D 2 B (8) — Initial Instrument Calibration. Calibration standards shall include concentrations at or below the regulatory limit or decision level, if these limits or levels are known by the laboratory, unless these concentrations are below the laboratory's demonstrated detection limits.

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

	Y	N	N/A		
INITIAL CALIBRATION					
1407	☐	☐	☐	740 D 2 B (9)	Initial Instrument Calibration. If a reference or mandated method does not specify the number of calibration standards, the minimum number is two, not including blanks or a zero standard. The laboratory shall have a standard operating procedure for determining the number of points for establishing the initial instrument calibration.
CONTINUING CALIBRATION					
1408	☐	☐	☐	740 D 2 C 1	Continuing instrument calibration verification. When an initial calibration is not performed on the day of analysis, the validity of the initial calibration shall be verified prior to sample analyses by a continuing instrument calibration check with each analytical batch. This provision does not apply to laboratories performing only simple test procedures.
1409	☐	☐	☐	740 D 2 C 2 A	Continuing instrument calibration verification. For essential element of continuing instrument calibration verification the laboratory shall include or reference the details of the continuing instrument calibration procedure, calculations and associated statistics in the standard operating procedure for the test method.
1410	☐	☐	☐	740 D 2 C 2 B	Continuing instrument calibration verification. For essential element of continuing instrument calibration verification the laboratory shall verify calibration for each compound, element, or other discrete chemical species, except for multi-component analytes such as Aroclors, Total Petroleum Hydrocarbons, or Toxaphene where a representative chemical related substance or mixture can be used.
1411	☐	☐	☐	740 D 2 C 2 C, I-IV	Continuing instrument calibration verification. For essential element of continuing instrument calibration verification, the laboratory shall perform a continuing instrument calibration verification as follows: _____(i.) At the beginning and end of each analytical batch. If an internal standard is used, only one verification needs to be performed at the beginning of the analytical batch; _____ (ii.) Whenever it is expected that the analytical system may be out of calibration or might not meet the verification acceptance criteria; _____(iii.) If the time period for calibration or the most previous calibration verification has expired; or _____(iv.) For analytical systems that contain a calibration verification requirement.
1412	☐	☐	☐	740 D 2 C 2 D	Continuing instrument calibration verification. Sufficient raw data records shall be retained to permit reconstruction of the continuing instrument calibration verification (e.g., or test method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor, or unique equations or coefficients used to convert instrument responses into concentrations). Continuing calibration verification records shall explicitly connect the continuing verification data to the initial instrument calibration.
1413	☐	☐	☐	740 D 2 C 2 E	Continuing instrument calibration verification. Criteria for the acceptance of a continuing instrument calibration verification shall be established (e.g., percent recovery or relative percent difference).
1414	☐	☐	☐	740 D 2 C 2 F	Continuing instrument calibration verification. If the continuing instrument calibration verification results obtained are outside established acceptance criteria, corrective actions performed. If routine corrective action procedures fail to produce a second consecutive (immediate) calibration verification within acceptance criteria, then either the laboratory has to demonstrate acceptable performance after corrective action with two successful calibration verifications, or a new initial instrument calibration shall be performed. If the continuing instrument calibration verification results obtained are outside established acceptance criteria, sample analyses shall not occur until the analytical system is calibrated or calibration verified. If samples are analyzed using a system on which the calibration has not yet been verified, the results shall be flagged.
1415	☐	☐	☐	740 D 2 C 2 F (i)	Continuing instrument calibration verification. Data associated with an unacceptable calibration verification may be fully useable under the following special condition: When the acceptance criteria for the continuing calibration verification are exceeded high (i.e., high bias) and there are associated samples that are nondetects, then those nondetects may be reported. Otherwise the samples affected by the unacceptable calibration verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.
1416	☐	☐	☐	740 D 2 C 2 F (ii)	Continuing instrument calibration verification. Data associated with an unacceptable calibration verification may be fully useable under the following special condition: When the acceptance criteria for the continuing calibration verification are exceeded low (i.e., low bias) those sample results may be reported if they exceed a maximum regulatory limit or decision level. Otherwise the samples affected by the unacceptable verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.
LOD/LOQ					

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

Y N N/A

LOD/LOQ

1424 ☐☐☐ 750 C 4 — Quality assurance. All laboratories shall have detailed written protocols in place to monitor the following quality controls: Measures to evaluate test method capability, such as method detection limits and quantitation limits or range of applicability such as linearity.

1433 ☐☐☐ 760 B 1 A — Limit of detection (excluding microbiology). The laboratory shall determine the LOD for the method for each target analyte of concern in the quality system matrices when the testing is conducted using approved methods listed in 40 CFR Part 136 for a program under the federal Clean Water Act, except when the procedure for Determination of Method Detection Limit at 40 CFR Part 136 Appendix B states the procedure is not applicable to a measurement.

1434 ☐☐☐ 760 B 1 B — Limit of detection (excluding microbiology). The laboratory shall determine the LOD for the method for each target analyte of concern in the quality system matrices when the test results are to be reported to the LOD (versus the limit of quantitation or working range of instrument calibration), according to 1VAC30-45-771 and 1VAC30-45-814. Where an LOD study is not perormed, the laboratory may not report a value below the limit of quantitation.

1435 ☐☐☐ 760 B 1 C — Limit of detection (excluding microbiology). When the LOD is required under subdivision 1 a or 1 b of 1VAC30-45-760 B, all sample processing steps of the analytical method shall be included in the determination of the LOD.

1436 ☐☐☐ 760 B 1 D — Limit of detection (excluding microbiology). The validity of the LOD shall be confirmed as described in 40 CFR Part 136 Appendix B as applicable, or by qualitative identification of the analyte(s) in a quality control sample in each quality system matrix containing the analyte at no more than two to three times the LOD for single analyte tests and one to four times the LOD for multiple analyte tests.

1437 ☐☐☐ 760 B 1 D — Limit of detection (excluding microbiology). This verification [of the LOD] shall be performed on every instrument that is to be used for analysis of samples and reporting of data.

1438 ☐☐☐ 760 B 2 A — Limit of quantitation (excluding microbiology). The laboratory shall determine the Limit of Quantitation (LOQ) for each analyte of concern according to a defined, documented procedure.

1439 ☐☐☐ 760 B 2 C — Limit of quantitation (excluding microbiology). The validity of the LOQ shall be confirmed by successful analysis of a QC sample containing the analytes of concern in each quality system matrix at a concentration at or below the LOQ or no more than two times the concentration of the claimed LOQ. A successful analysis is one where the recovery of each analyte is within the established test method acceptance criteria or client data quality objectives for accuracy. This single analysis is not required if the bias and precision of the measurement system is evaluated at the LOQ.

SELECTIVITY

1427 ☐☐☐ 750 C 7 — Quality assurance. All laboratories shall have detailed written protocols in place to monitor the following quality controls: Measures to assure the selectivity of the test for its intended purpose.

1445 ☐☐☐ 760 B 4 — Evaluation of selectivity. The laboratory shall evaluate selectivity by following the checks established within the method. These checks may include mass spectral tuning, second column confirmation, ICP inter-element interference checks, chromatography retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors.

QC

1417 ☐☐☐ 750 A — Quality assurance. General. The laboratory shall have quality control procedures for monitoring the validity of environmental tests undertaken.

1418 ☐☐☐ 750 A — Quality assurance. General. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results.

1419 ☐☐☐ 750 A — Quality assurance. General. The monitoring shall be planned and reviewed and may include, but not limited to the following:
___Regular use of certified reference materials or internal quality control using secondary reference materials or both.
___Participation in interlaboratory comparison or proficiency-testing program.
___Replicate tests or calibrations using the same or different methods.
___Retesting of retained samples.
___Correlation of results for different characteristics of a sample (e.g., total phosphate should be greater than or equal to orthophosphate)

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

	Y	N	N/A		
QC					
1420	☐	☐	☐	750 B	Noncommercial environmental laboratories that analyze environmental samples using other types of testing such as toxicity, radiochemical, or asbestos testing shall meet the quality control standards for the specific method and the specific type of testing in the 2009 TNI Standards for Environmental Laboratories.
1421	☐	☐	☐	750 C 1	Quality assurance. All laboratories shall have detailed written protocols in place to monitor the following quality controls: Positive and negative controls to monitor tests such as blanks, spikes, reference toxicants.
1422	☐	☐	☐	750 C 2	Quality assurance. All laboratories shall have detailed written protocols in place to monitor the following quality controls: Tests to define the variability or repeatability of the laboratory results or both such as replicates.
1423	☐	☐	☐	750 C 3	Quality assurance. All laboratories shall have detailed written protocols in place to monitor the following quality controls: Measures to assure the accuracy of the test method including calibration or continuing calibrations or both, use of certified reference materials, proficiency test samples, or other measures.
1429	☐	☐	☐	760 A 1	Quality control. General. The quality control protocols specified by the laboratory's SOPs shall be followed (1VAC30-45-730 C).
1430	☐	☐	☐	760 A 1	Quality control. General. The laboratory shall ensure that either the (i) applicable essential standards outlined in this section through 1VAC30-45-775, 1VAC30-45-791 through 1VAC30-45-798, and 1VAC30-45-811 or (ii) mandated methods or regulations, whichever are more stringent, are incorporated into their SOPs. When it is not apparent which is more stringent, the quality controls in the mandated method or regulations are to be followed.
1431	☐	☐	☐	760 A 2	Quality control. General. All quality control measures shall be assessed and evaluated on an ongoing basis and quality control acceptance criteria shall be used to determine the validity of the data.
1432	☐	☐	☐	760 A 2	Quality control. General. The laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exists.

EQUIPMENT

1335	☐	☐	☐	720 A	The laboratory shall be furnished with all items of equipment, including reference materials, required for the correct performance of tests for which certification is sought. The laboratory shall maintain records of reference materials sufficient to provide proper performance of tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this article are met.
1336	☐	☐	☐	720 B	All equipment shall be properly maintained, inspected and cleaned.
1337	☐	☐	☐	720 B	Maintenance procedures shall be documented.
1338	☐	☐	☐	720 C	Any item of the equipment that has been subjected to overloading or mishandling, or that gives suspect results, or has been shown by verification or otherwise to be defective shall be taken out of service immediately, clearly identified as being out of service and, wherever possible, stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.
1339	☐	☐	☐	720 D	Each item of equipment including reference materials shall be labeled, marked or otherwise identified to indicate its calibration status.
1340	☐	☐	☐	720 E	Records of each major item of equipment significant to the tests performed shall be maintained. These records shall include documentation on all routine and non-routine maintenance activities. The laboratory shall maintain records of reference materials sufficient to provide proper performance of tests. The records shall include: ___The name of the item of equipment; ___The manufacturer's name, type identification, and serial number or other unique identification; ___Date received and date placed in service (if available); ___Current location, where appropriate; ___If available, condition when received (e.g. new, used, reconditioned); ___Copy of the manufacturer's instructions, where available; ___Dates and results of calibrations or verifications or both and date of the next calibration or verification; ___Details of maintenance carried out to date and planned for the future; and ___History of any damage, malfunction, modification or repair.

SUPPORT EQUIPMENT

1389	☐	☐	☐	740 D 1 A	Calibration - Support Equipment. All support equipment shall be maintained in proper working order.

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

Y N N/A

SUPPORT EQUIPMENT

1390	☐	☐	☐	740 D 1 A	Calibration - Support Equipment. The records of all repair and maintenance activities, including service calls, shall be kept.
1391	☐	☐	☐	740 D 1 B	Calibration - Support Equipment. All support equipment shall be calibrated or verified at least annually, using NIST traceable references when available, over the entire range of use. The results of such calibration shall be within the specifications required of the application for which this equipment is used. If not, the laboratory shall either (i) remove the equipment from service until repaired or (ii) maintain records of established correction factors to correct all measurements.
1392	☐	☐	☐	740 D 1 C	Calibration - Support Equipment. Raw data records shall be retained to document support equipment performance.
1393	☐	☐	☐	740 D 1 D	Calibration - Support Equipment. On each day the equipment is used, balances, ovens, refrigerators, freezers, and water baths shall be checked in the expected use range, with NIST traceable references where available. The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used.
1394	☐	☐	☐	740 D 1 E	Calibration - Support Equipment. Mechanical volumetric dispensing devices including burettes (except Class A glassware) shall be checked for accuracy on at least a quarterly use basis. Glass microliter syringes are to be considered in the same manner as Class A glassware, but shall come with a certificate attesting to established accuracy or the accuracy shall be initially demonstrated and documented by the laboratory.
1395	☐	☐	☐	740 D 1 F	Calibration - Support Equipment. For chemical tests, the temperature, cycle time, and pressure of each run of autoclaves shall be documented by the use of appropriate chemical indicators or temperature recorders and pressure gauges.
1396	☐	☐	☐	740 D 1 G (1)	Calibration - Support Equipment. For biological tests that employ autoclave sterilization, the performance of each autoclave shall be initially evaluated by establishing its functional properties and performance, for example heat distribution characteristics with respect to typical uses. Autoclaves shall meet specified temperature tolerances. Pressure cookers fitted only with a pressure gauge are not recommended for sterilization of media or decontamination of wastes.
1397	☐	☐	☐	740 D 1 G (2)	Calibration - Support Equipment. Records of autoclave operations including temperature and time shall be maintained. This shall be done for every cycle. Acceptance and rejection criteria shall be established and used to evaluate the autoclave efficiency and effectiveness.

REAGENTS & MEDIA

1374	☐	☐	☐	730 J 1	Documentation and labeling of standards and reagents. The laboratory shall retain records for all standards, reagents, reference materials and media including records for the following: __ the manufacturer/vendor, __ the manufacturer's Certificate of Analysis or purity (if available), __ the date of receipt, __ the recommended storage conditions, and __ an expiration date after which the material shall not be used unless its reliability is verified by the laboratory.
1375	☐	☐	☐	730 J 2	Documentation and labeling of standards and reagents. Original containers (such as provided by the manufacturer or vendor) shall be labeled with an expiration date if this date is provided by the manufacturer or vendor.
1376	☐	☐	☐	730 J 3	Documentation and labeling of standards and reagents. Records shall be maintained on standard and reference material preparation. These records shall indicate: __ traceability to purchased stocks or neat compounds, __ reference to the method of preparation, __ date of preparation, __ expiration date, and __ preparer's initials.
1377	☐	☐	☐	730 J 4	Documentation and labeling of standards and reagents. Sufficient identification of containers of prepared reagents and standards shall be provided to ensure proper performance of tests.
1426	☐	☐	☐	750 C 6	Quality assurance. All laboratories shall have detailed written protocols in place to monitor the following quality controls: Selection and use of reagents and standards of appropriate quality.

PURCHASING (SERVICES & SUPPLIES)

1321	☐	☐	☐	690 A	The laboratory shall have a policy and procedures for the selection and purchasing of services and supplies it uses that affect the quality of the environmental tests.

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

Y N N/A

PURCHASING (SERVICES & SUPPLIES)

1322 ☐ ☐ ☐ 690 A — Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the environmental tests.

1323 ☐ ☐ ☐ 690 B — The laboratory shall ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.

1324 ☐ ☐ ☐ 690 C — The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for tests.

1373 ☐ ☐ ☐ 730 J — Documentation and labeling of standards and reagents. Documented procedures shall exist for the reception and storage of consumable materials used for the technical operations of the laboratory.

1386 ☐ ☐ ☐ 740 C 1 — Reference standards. The laboratory shall have a program and procedure for the calibration of its reference standards. Reference standards of measurement shall be calibrated by a body that can provide traceability as described in 1VAC30-45-740 B. Such reference standards of measurement held by the laboratory (such as Class S or equivalent weights or traceable thermometers) shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards would not be invalidated. Where commercially available, this traceability shall be to a national standard of measurement.

1387 ☐ ☐ ☐ 740 C 2 — Reference materials. Reference materials shall, where commercially available, be traceable to SI units of measurement, or to certified reference materials. Where possible, traceability shall be to national or international standards of measurement, or to national or international standard reference materials.

DATA ANALYSIS

1425 ☐ ☐ ☐ 750 C 5 — Quality assurance. All laboratories shall have detailed written protocols in place to monitor the following quality controls: Selection of appropriate formulae to reduce raw data to final results such as regression analysis, comparison to internal and external standard calculations, and statistical analyses.

RECORDS

1278 ☐ ☐ ☐ 630 — The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. This system shall produce unequivocal, accurate records that document all laboratory activities.

1279 ☐ ☐ ☐ 640 A — The laboratory shall have a recordkeeping system that allows historical reconstruction of all laboratory activities that produced the analytical data. The history of the sample shall be readily understood through the documentation. This shall include inter-laboratory transfers of samples or extracts or both.

1280 ☐ ☐ ☐ 640 B — The records shall include the identity of personnel involved in sampling, sample preservation, sample receipt, preparation, calibration or testing, all documentation sent by the person transmitting the sample, including a chain of custody record form, if utilized.

1281 ☐ ☐ ☐ 640 C — The laboratory shall document all information relating to the laboratory facility's equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification.

1282 ☐ ☐ ☐ 640 D — The laboratory shall have a recordkeeping system that facilitates the retrieval of all working files and archived records for inspection and verification purposes, e.g., set format for naming electronic files.

1283 ☐ ☐ ☐ 640 E — Responsible staff shall sign or initial all changes to records. The reason for changes to records shall be clearly indicated in the records such as "sampled by," "prepared by," or "reviewed by."

1284 ☐ ☐ ☐ 640 F — All generated data except those that are generated by automated data collection systems, shall be recorded directly, promptly and legibly in permanent ink.

1285 ☐ ☐ ☐ 640 G — Entries in records shall not be obliterated by methods such as erasures, overwritten files or markings. All corrections to recordkeeping errors shall be made by one line marked through the error. The individual making the correction shall sign or initial and date the correction. These criteria also shall apply to electronically maintained records.

1287 ☐ ☐ ☐ 650 A — The laboratory shall keep all records, certificates and reports as required by applicable state and federal recordkeeping laws and regulations. The laboratory shall safely store these records and hold them secure.

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

	Y	N	N/A		
RECORDS					
1288	☐	☐	☐	650 B	The laboratory shall retain all records for a minimum of three years from generation of the last entry in the records, or longer, if required by an applicable regulatory program, whichever is greater. The laboratory shall maintain all information necessary for the historical reconstruction of data, including all original observations, calculations and derived data, calibration records and a copy of the test report.
1290	☐	☐	☐	650 D	The laboratory shall establish a record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation storage and reporting.
1291	☐	☐	☐	650 E	The laboratory shall protect these records against fire, theft, loss, environmental deterioration, vermin and, in the case of electronic records, electronic or magnetic sources.
1292	☐	☐	☐	650 F	The laboratory shall have a plan to ensure that the records are maintained or transferred in the event that a laboratory transfers ownership or goes out of business. In addition, in cases of bankruptcy, the laboratory shall follow appropriate regulatory and state legal requirements concerning laboratory records.
1296	☐	☐	☐	660 B 2	Laboratory support activities: The laboratory shall retain the following documents and data: A written description or reference to the specific test method used which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value.
1299	☐	☐	☐	660 B 5	Laboratory support activities: The laboratory shall retain the following documents and data: Correspondence relating to laboratory activities.
1300	☐	☐	☐	660 B 6	Laboratory support activities: The laboratory shall retain the following documents and data: All corrective action reports, audits and audit responses.
RECORDS-RAW DATA					
1295	☐	☐	☐	660 B 1	Laboratory support activities: The laboratory shall retain the following documents and data: All original raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts' work sheets and data output records (chromatograms, strip charts, and other instrument response readout records).
1303	☐	☐	☐	660 C	Analytical records: The laboratory shall retain essential information associated with analytical documents, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs. This information includes, but is not limited to all manual calculations, e.g., manual integrations; sample preparation; standard and reagent origin, receipt, preparation, and use; quality control protocols and assessment; and method performance criteria.
RECORDS-ELECTRONIC					
1286	☐	☐	☐	640 H	The laboratory shall keep computer and electronic data records in accordance with the pertinent provisions of this section, 1VAC30-45-650C and E and 1VAC30-45-730 K.
1289	☐	☐	☐	650 C	Records that are stored only on electronic media shall be supported by the hardware and software necessary for their retrieval. Records that are stored or generated by computers or personal computers shall have hard copy or write-protected backup copies.
REPORTING/REPORTS					
1221	☐	☐	☐	50 A	Noncommercial environmental laboratories shall be certified based on the specific test methods or analysis, monitoring or measurement required by regulatory permit or other requirement under the Virginia Air Pollution Control Law, Virginia Waste Management Act or Virginia Water Control Law, the regulations promulgated under these laws, and by permits and orders issued and in accordance with these laws or regulations.
1297	☐	☐	☐	660 B 3	Laboratory support activities: The laboratory shall retain the following documents and data: Copies of final reports.
1317	☐	☐	☐	670 D 2	To the extent possible, samples shall be reported only if all quality control measures are acceptable. If a quality control measure is found to be out of control, and the data are to be reported, all samples associated with the failed quality control measure shall be reported with the appropriate data qualifiers.
1624	☐	☐	☐	860 A	Laboratory reports. The results of each test or series carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively. The results shall normally be reported in a test report required by regulation and shall include all the information necessary for the interpretation of the test results and all information required by the method used.
1625	☐	☐	☐	860 B	Laboratory reports. Where the certificate or report contains results of tests performed by subcontractors, these results shall be clearly identified by subcontractor name or applicable certification number.

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

Y N N/A

REPORTING/REPORTS

1626 ☐ ☐ ☐ 860 C — Laboratory reports. After issuance of the report, the laboratory report shall remain unchanged. Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Test Report or Test Certificate, serial number... (or as otherwise identified)," or equivalent form of wording. Such amendments shall meet all the relevant requirements of this article.

ORGANIZATION

1223 ☐ ☐ ☐ 70 K 3 — The laboratory shall post the most recent certificate of certification and any addenda to the certificate issued by DCLS in a prominent place in the laboratory facility.

1277 ☐ ☐ ☐ 620 — The laboratory shall specify and document the functional responsibility, level of authority, and interrelationship or lines of communication of all personnel who manage, perform or verify work affecting the quality of tests, analyses, measurements and monitoring. One person may cover more than one organizational function. Each manager and employee of the laboratory shall have a clear understanding of his or her duties and responsibilities and the relationship of those responsibilities to the overall work of the laboratory.

DATA INTEGRITY

1302 ☐ ☐ ☐ 660 B 8 — Laboratory support activities: The laboratory shall retain the following documents and data: Results of data review, verification, and cross-checking procedures.

1369 ☐ ☐ ☐ 730 I — Data verification. Calculations and data transfers shall be subject to appropriate checks.

1370 ☐ ☐ ☐ 730 I — Data verification. The laboratory shall establish standard operating procedures to ensure that the reported data are free from transcription and calculation errors.

1371 ☐ ☐ ☐ 730 I — Data verification. The laboratory shall establish standard operating procedures to ensure that all quality control measures are reviewed and evaluated before data are reported.

1372 ☐ ☐ ☐ 730 I — Data verification. The laboratory also shall establish standard operating procedures addressing manual calculations including manual integrations.

1378 ☐ ☐ ☐ 730 K 1 — Where computers, automated equipment, or microprocessors are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data, the laboratory shall ensure the computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use.

1379 ☐ ☐ ☐ 730 K 2 — Where computers, automated equipment, or microprocessors are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data, the laboratory shall ensure the procedures are established and implemented for protecting the integrity of data, such as integrity of data entry or capture, data storage, data transmission and data processing.

1380 ☐ ☐ ☐ 730 K 3 — Where computers, automated equipment, or microprocessors are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data, the laboratory shall ensure the computer and automated equipment are maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data.

1381 ☐ ☐ ☐ 730 K 4 — Where computers, automated equipment, or microprocessors are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data, the laboratory shall ensure the appropriate procedures are established and implemented for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

QUALITY MANUAL

1250 ☐ ☐ ☐ 610 A 1 — The laboratory shall document its quality system in a quality manual.

1251 ☐ ☐ ☐ 610 A 1 — The quality manual shall reflect all quality assurance and quality control practices and programs used by the laboratory. The required elements of the quality system may be described in more than one document.

1252 ☐ ☐ ☐ 610 A 2 — The quality manual shall be maintained current under the responsibility of the quality assurance officer.

1253 ☐ ☐ ☐ 610 A 3 — The quality manual and any related documents shall be communicated to, understood by, available to, and implemented by all laboratory personnel.

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

Y N N/A

QUALITY MANUAL

1254	☐	☐	☐	610 A 4	The quality manual shall include but not be limited to the elements listed in section 1VAC30-45 610 B and C.
1255	☐	☐	☐	610 B 1-6	The elements of a quality manual shall include but not be limited to: __ A document title; __ The laboratory's full name and address; __ The name, address (if different from the laboratory's), and telephone number of the responsible official, laboratory manager, and quality assurance officer; __ The laboratory facility or facilities covered by the quality manual; __ Signed and dated concurrence, with appropriate titles, of the responsible official, laboratory manager, and quality assurance officer; and __ The effective date of the quality manual.
1256	☐	☐	☐	610 B 7	The elements of a quality manual shall include but not be limited to: Table of contents and applicable lists of references, glossaries, and appendices.
1257	☐	☐	☐	610 B 8	The elements of a quality manual shall include but not limited to: A quality policy statement, including objectives of the quality system and commitment to ethical laboratory practices and to upholding the requirements of the standards of 1VAC30-45.
1258	☐	☐	☐	610 C 1	The elements of a quality manual shall include or reference but not be limited to: The organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts.
1259	☐	☐	☐	610 C 2	The elements of a quality manual shall include or reference but not be limited to: Job descriptions of key staff and reference to the job descriptions of other staff.
1260	☐	☐	☐	610 C 3	The elements of a quality manual shall include or reference but not be limited to: Processes or procedures for establishing that personnel have adequate training and experience in the duties they are expected to carry out and are receiving any needed training.
1261	☐	☐	☐	610 C 4	The elements of a quality manual shall include or reference but not be limited to: Mechanisms for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work.
1262	☐	☐	☐	610 C 5	The elements of a quality manual shall include or reference but not be limited to: Procedures to ensure that all records required by 1VAC30-45 are retained, as well as procedures for control and maintenance of documentation through a document control system that ensures that all standard operating procedures, manuals, or documents clearly indicate the time period during which the procedure or document was in force.
1263	☐	☐	☐	610 C 6	The elements of a quality manual shall include or reference but not be limited to: Procedures for dealing with complaints.
1264	☐	☐	☐	610 C 7	The elements of a quality manual shall include or reference but not be limited to: Procedures for audits and data review.
1265	☐	☐	☐	610 C 8	The elements of a quality manual shall include or reference but not be limited to: Verification practices that may include inter-laboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes.
1266	☐	☐	☐	610 C 9	The elements of a quality manual shall include or reference but not be limited to: Procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur.
1267	☐	☐	☐	610 C 10	The elements of a quality manual shall include or reference but not be limited to: The laboratory management arrangements for permitting departures from documented policies and procedures or from standard specifications when the departures are planned and controlled.
1268	☐	☐	☐	610 C 11	The elements of a quality manual shall include or reference but not be limited to: The major equipment and reference measurement standards used as well as the physical facility and environment used by the laboratory in conducting tests.
1269	☐	☐	☐	610 C 12	The elements of a quality manual shall include or reference but not be limited to: Procedures for calibration, verification and maintenance of equipment.
1270	☐	☐	☐	610 C 13	The elements of a quality manual shall include or reference but not be limited to: A list of all technology/methods under which the laboratory performs its certified testing.
1271	☐	☐	☐	610 C 14	The elements of a quality manual shall include or reference but not be limited to: Procedures for achieving traceability of measurements, including standards.
1272	☐	☐	☐	610 C 15	The elements of a quality manual shall include or reference but not be limited to: Procedures for receiving, handling, storing, and disposing of submitted samples.

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

Y N N/A

QUALITY MANUAL

1273 ☐ ☐ ☐ 610 C 16 — The elements of a quality manual shall include or reference but not be limited to: Reference to procedures for reporting analytical results.

1274 ☐ ☐ ☐ 610 C 17 — The elements of a quality manual shall include but not be limited to: Policy addressing the use of unique electronic signatures, where applicable.

1276 ☐ ☐ ☐ 610 D 2 — The quality assurance manual shall be reviewed and approved by the quality assurance officer, the laboratory manager, and the responsible official at least annually.

SUBCONTRACTING

1318 ☐ ☐ ☐ 680 A — Where a laboratory subcontracts any part of the testing covered under this chapter, the testing shall only be subcontracted to a laboratory certified under 1VAC30-46.

1319 ☐ ☐ ☐ 680 B — The report from the subcontractor shall be a separate part of the laboratory report and identified as laboratory testing done by a subcontractor.

1320 ☐ ☐ ☐ 680 C — The laboratory shall retain records demonstrating that subcontracting requirements have been met.

COMPLAINTS

1325 ☐ ☐ ☐ 700 — The laboratory shall have documented policy and procedures for the resolution of complaints about the laboratory's activities.

1326 ☐ ☐ ☐ 700 — Where a complaint or any other circumstance raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this chapter or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with 1VAC30-45-670 A. Records of the complaint and subsequent actions shall be maintained.

CORRECTIVE ACTION

1316 ☐ ☐ ☐ 670 D 1 — In addition to providing acceptance criteria and specific protocols for corrective actions in the method standard operating procedures, the laboratory shall implement general procedures to be followed to determine consistently when departures from documented policies, procedures and quality control have occurred. These procedures may include but are not limited to the following:

___Identify the individual or individuals responsible for assessing each quality control data type;
___Identify individual or individuals responsible for initiating or recommending corrective actions or both;
___Define how the analyst shall treat a data set if the associated quality control measurements are unacceptable;
___Specify how out-of-control situations and subsequent corrective actions are to be documented; and
___Specify procedures for management (including quality assurance officer) to review corrective action reports.

INTERNAL AUDITS

1307 ☐ ☐ ☐ 670 A 1 — The laboratory shall arrange for annual internal audits to verify that its operations continue to comply with the requirements of the laboratory's quality system. It is the responsibility of the quality assurance officer to plan and organize audits as required by a predetermined schedule and requested by management.

1308 ☐ ☐ ☐ 670 A 2 — Trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited, shall carry out these audits. Personnel shall not audit their own activities except when it can be demonstrated that an effective audit will be carried out.

1309 ☐ ☐ ☐ 670 A 3 — Where audit findings cast doubt on the correctness or validity of the laboratory's calibrations or test results, the laboratory shall take immediate corrective actions.

1310 ☐ ☐ ☐ 670 A 4 — A laboratory may have an audit performed under contract by an outside source competent to audit the laboratory's operations.

1314 ☐ ☐ ☐ 670 C — Audit review. All audit and review findings and any corrective actions that arise from them shall be documented.

1315 ☐ ☐ ☐ 670 C — Audit review. The laboratory management shall ensure that these audits and corrective actions are discharged within the agreed time frame as indicated in the quality manual or standard operating procedures or both.

PERSONNEL

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

	Y	N	N/A		
PERSONNEL					
1224	☐	☐	☐	90 A	The certified laboratory shall notify DCLS in writing of any changes in key certification criteria within 30 days of the change. Key certification criteria are laboratory ownership, location, key personnel, and major instrumentation.
1234	☐	☐	☐	220 A	The laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.
1235	☐	☐	☐	220 B	The laboratory manager shall ensure that the training of the laboratory personnel is kept up to date.
1236	☐	☐	☐	220 C	Laboratory personnel shall be responsible for complying with all quality systems requirements set out in 1VAC30-45-600 et seq. that are pertinent to their assigned functions.
1237	☐	☐	☐	220 D	The laboratory manager shall ensure that laboratory personnel have demonstrated initial and on-going capability to perform their assigned functions. (See 1VAC-45-730 E and F).
1238	☐	☐	☐	220 E	The laboratory manager shall maintain records on the relevant qualifications, training, skills and experience of the laboratory personnel, including records on demonstrated proficiency for each test method.
1304	☐	☐	☐	660 D 1	Administrative records: The laboratory shall maintain the following administrative records: Personnel qualifications, experience and training records.
1306	☐	☐	☐	660 D 3	Administrative records: The laboratory shall maintain the following administrative records: A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record.
TRACEABILITY					
1383	☐	☐	☐	740 B 1	Traceability of calibration. The laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.
1385	☐	☐	☐	740 B 3	Traceability of calibration. Where traceability of measurements to the International System of Units (SI) is not possible or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods or consensus standards, are required. The laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of inter-laboratory comparisons, proficiency testing, or independent analysis.
PROFICIENCY TESTING					
1240	☐	☐	☐	510 B	The laboratory's management and all analysts shall ensure that all PT samples are managed, analyzed, and reported in the same manner as real environmental samples utilizing the same staff, methods as used for routine analysis of that analyte, procedures, equipment, and facilities.
1241	☐	☐	☐	510 B	When analyzing a PT sample, the laboratory shall employ the same calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates and other procedures as used when analyzing routine samples.
1242	☐	☐	☐	510 C 1	Laboratory management or staff shall not send any PT sample, or portion of a PT sample, to another laboratory for any analysis for which the laboratory seeks certification or is certified prior to the time the results of the study are released.
1243	☐	☐	☐	510 C 2	Laboratory management or staff shall not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks accreditation or is accredited prior to the time the results of the study are released.
1244	☐	☐	☐	510 C 3	Laboratory management or staff shall not communicate with any individual at another laboratory (including intra-company communication) concerning PT samples prior to the time the results of the study are released.
1245	☐	☐	☐	510 C 4	Laboratory management or staff shall not attempt to obtain the assigned value of any PT sample from the PT provide prior to the time the results of the study are released.
1246	☐	☐	☐	510 D	Maintenance of records: The laboratory shall maintain copies of all written, printed, and electronic records, including but not limited to bench sheets, instrument strip charts or printouts, data calculations, and data reports, resulting from the analysis of any PT sample for three years or for as long as is required by the applicable regulatory program. These records shall include a copy of the PT study report forms used by the laboratory to record PT results. All of these laboratory records shall be made available to the DCLS assessors during on-site assessments of the laboratory.
1301	☐	☐	☐	660 B 7	Laboratory support activities: The laboratory shall retain the following documents and data: Proficiency test results and raw data.

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

QUALITY SYSTEM

Y N N/A

PROFICIENCY TESTING

1627 ☐ ☐ ☐ 520 C 1 When a laboratory receives a PT study result of "not acceptable,", the laboratory shall determine the cause for the failure and perform and document corrective action. The corrective action documentation shall be completed within 30 days of receiving the "not acceptable" PT study result and be submitted to DCLS upon request.